

Eric Kuhrt
U.S.S.N. 10/008,778
Attorney Docket: 068911.0076
Page 6 of 11

REMARKS

Reexamination and reconsideration in light of the foregoing amendments and following remarks is respectfully requested.

I. AMENDMENTS

Claims 1 through 27 are pending. Claims 1 through 12, 14, 16 and 18 - 27 have been withdrawn from further consideration since they have been found to read on non-elected inventions. The finality of the requirement is acknowledged.

Claim 13 has been amended to further recite that the administration of the compositions contemplated is to a mammal having osteoarthritis, rheumatoid arthritis or acute pain. Support for the amendments may be found throughout the specification (see e.g., paragraph [0048] of the published application. Accordingly, these amendments and new claims do not raise an issue of new matter and entry thereof is respectfully requested.

Claims 13, 15 and 17 are pending. Claims 13, 15 and 17 have been rejected.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 13, 15 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 363211219 ("JP"). At page 3 of the Action, the Examiner has maintained the argument that "*JP teaches that a composition to prevent dental caries is made which reads on the invention.*" Essentially, the Examiner has maintained the rejections insofar as "*the claims do not require a patient to suffer from the claimed diseases/disorders*" (see Action at page 3). Applicant has amended Claim 13 (and thus, Claims 15 and 17 depending from

Eric Kuhrt
U.S.S.N. 10/008,778
Attorney Docket: 068911.0076
Page 7 of 11

Claim 13) to be limited to the administration of the compositions of the invention to a mammal having osteoarthritis, rheumatoid arthritis or acute pain.

As previously maintained, JP does not teach methods for the treatment of osteoarthritis, rheumatoid arthritis or acute pain. The invention of Claims 13, 15 and 17 as amended is specifically directed to the treatment of mammals having osteoarthritis, rheumatoid arthritis or acute pain. Because JP relates exclusively to the "*preventing the proliferation of cariogenic bacteria*" (see JP, paragraph labeled PURPOSE) JP does not anticipate the methods of Claims 13, 15, and 17.

Accordingly, Applicant respectfully request reconsideration and withdrawal of the rejections in light of the amendments and remarks found herein.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 13, 15 and 17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over FR 002590589 ("FR"), GB 2072657 ("GB"), Forster *et al.* U.S. Patent No. 4,640,841 ("Forster"), Ting *et al.* U.S. Patent No. 6,020,019 ("Ting"), taken with JP.

At page 3 of the Action it is stated that "FR, GB Forster and Ting all teach the claimed compound". And further, that "JP teaches to administer it to prevent dental caries. Thus, it would have been *prima facie obvious* to administered <sic> the claimed composition."

Arguably, FR, GB, Forster and Ting relate to iso-alpha acids and to preparation methods of the same without more. Note that none of these references is concerned with bioavailability of pharmaceutical compositions of iso-alpha acids. In addition, none of these references is concerned with pharmaceutical compositions having the property recited in the claims of the invention (*i.e.*, comprising a therapeutic quantity of

Eric Kuhrt
U.S.S.N. 10/008,778
Attorney Docket: 068911.0076
Page 8 of 11

a COX-2 inhibitor having an IC₅₀-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity).

JP is adduced to provide the teaching or suggestion to use iso-alpha acids therapeutically. Applicant aver that in light of the amendments herein, the obviousness rejections should be reconsidered and withdrawn.

Specifically, FR purports to teach a method to process alpha and beta acids by photochemically irradiation of the same under pressure. FR is merely a process patent which has no relevance to therapeutic modalities. Furthermore, FR relates exclusively to beer manufacturing. Accordingly, FR is not concerned with the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

The GB reference relates to beta acids. Specifically, this reference purports to teach beer manufacturing methods suitable to obtain hulupones. In a variation of the beer making processes contemplated, patentee advocates mixing such hulupones with isohumulones to provide a beer soluble product which, as a bitter constituent, has all the taste properties of natural hops. Accordingly, GB is not concerned with the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

Forster relates to hops extraction with supercritical carbon dioxide at pressures of about 100 to about 300 bar and temperatures above 100°C to yield a resin extract of first grade quality similar in its composition to an extract obtained with methylene chloride. The process is said to provide additional hop substances at higher total yield which increase the potential bitterness of the beer. Accordingly, Forster is not concerned with

Eric Kuhrt
U.S.S.N. 10/008,778
Attorney Docket: 068911.0076
Page 9 of 11

the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

Ting relates to the use of CO₂ as a reaction solvent in the hydrogenation of organic compounds. The method is said to be useful for making tetrahydroiso-alpha-acids from alpha-acids, iso-alpha-acids, or beta-acids. While this patent does relate to certain iso-alpha acids, this patent is not concerned with the treatment of the indications addressed by the instant application. Similarly, Ting is not concerned with the bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity.

JP relates exclusively to the "*preventing the proliferation of cariogenic bacteria*" (see JP, paragraph labeled PURPOSE). Accordingly, JP is not concerned with the treatment of any of the conditions addressed by the instant invention, bioavailability of pharmaceutical preparations of iso-alpha acids or with gastrointestinal or cardiovascular toxicity. JP thus, does not cure the deficiencies of either one of the primary references cited.

Coupled to the absence of any teaching or suggestion, there is no motivation to modify the art cited to arrive at the invention of amended claims 13, 15 and 17. Similarly, one of skill in the art –without the benefit of the teaching of Applicant's disclosure – would not have had a reasonable expectation of success in treating osteoarthritis, rheumatoid arthritis or acute pain using the selected pharmaceutical compositions of the invention. Simply stated, patents related to make testier beer in combination with a patent related to prevent dental caries cannot possibly lead one of

Eric Kuhrt
U.S.S.N. 10/008,778
Attorney Docket: 068911.0076
Page 10 of 11

skill to arrive to a pharmaceutical preparation for therapeutic uses according to the instant invention absent more.

For the foregoing reasons, applicants aver that a *prima facie* case of obviousness of the claimed invention has not been established.

Accordingly, it is respectfully requested that the rejections of Claims 13, 15 and 17 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

<<CONCLUSION SECTION ON THE NEXT PAGE>>

Eric Kuhrt
U.S.S.N. 10/008,778
Attorney Docket: 068911.0076
Page 11 of 11

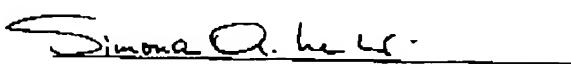
III. CONCLUSION

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended claims 13, 15 and 17 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

A Request for a Three (3) Month Extension of Time, up to and including August 18, 2005 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,
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